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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Bowman

Appeal No. ----

Application Serial No.: 09/737,185

Group No.: 1743

Filed: 12/14/2000

Confirmation No.: 9139

Examiner: Gakh, Yelena G.

For: **PAPERLESS CHAIN OF CUSTODY EVIDENCE FOR LAB SAMPLES**

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

Third Supplemental Appeal Brief

This Third Supplemental Appeal Brief is being transmitted in this application with respect to the Notice of Appeal filed June 12, 2006, and subsequent to the Appeal Brief filed November 17, 2005, with respect to the Notice of Appeal filed on June 28, 2005. This brief is prompted by the Notification of Non-Compliant Appeal Brief dated March 18, 2008. The Appeal Brief fee was paid with the earlier brief. Commissioner is hereby authorized to charge any additional fees that may be required to Deposit Account 501923.

This brief contains these items under the following headings, and in the order set forth below:

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APPELLANT'S BRIEF

1. Real Party in Interest

The real party in interest in this appeal is GBF, Inc.

2. Related Appeals and Interferences

There are no appeals or interferences that will directly affect or be directly affected by, or have a bearing on the Board's decision in this appeal.

3. Status of the Claims

Claims 1-21, 38 and 40-44 remain in the case with none of the claims being allowed or allowable. Claims 22-37 and 39 were previously cancelled without prejudice. Claims 1-21, 38, and 40-44 are the subject of this appeal.

4. Status of the Amendments

No amendment was submitted after the final Office Action mailed January 10, 2006.

5. Summary of Claimed Subject Matter

Applicant's claimed invention relates to improvements in identification, logistics control, and information management for biomedical specimens collected for diagnostic or toxicology testing. Diagnostic and toxicology specimens are typically collected for analytical testing from donors at collection sites such as hospitals, clinics, or doctors' offices. These specimens are collected in primary specimen containers specifically designed to completely and safely contain the specimens during handling and shipment in order to preserve the integrity of the specimens and to protect the health of persons who come in contact with the containers. In addition, primary toxicological specimen containers are typically provided with tamperproof locks or seals to ensure that the integrities of the toxicological specimens are not breached by unauthorized persons or by mishandling of the containers.

As claimed in independent Claim 1 and the claims dependent thereon, the present invention provides a diagnostic specimen system for identifying and controlling biomedical or toxicology specimens and managing information associated with the specimens. Diagnostic systems test for disease and the like. Toxicology tests look for toxic substances, including illegal drugs. The system provides a diagnostic or toxicology specimen container having an electronic memory tag for remote, non-contact recording and reading of data stored therein. Other claims are directed to embodiments of a method of using the system to manage information associated with the specimens.

The diagnostic specimen system includes a population (step 10, figure 4) of biomedical specimen collection vessels, such as the vessel 1, shown in Figure 1. (Inherently, the vessel distribution facility is the place where the activities described at page 12, line 17 to page 13, line 2 take place. Since this passage says that the codes 7 are correlated and stored on a central computer database and "then supplied" to multiple specimen collection sites, there must be a vessel distribution facility where the correlation and storage takes place before the supplying (i.e. distribution) of the specimen containers to the specimen collection sites takes place.) Attached to each of the vessels 1 is a wireless electronic memory tag 3. The tags 3 remain attached to the vessels 1 as each is transported between a vessel distribution facility (such as a vendor's warehouse), a specimen collection facility (such as a doctor's office), and a specimen testing laboratory facility (such as a laboratory), as depicted by the flowchart of Figure 4.

Also, in various embodiments, the memory tags 3 store data representing an identification code for the vessel 1, the identity of the supplier of the vessel 1, and product information about the vessel 1. The data may relate to the specimen donor and identify the specimen contained in the vessel 1. The data may also define analytical tests to be performed on the specimen. Each

vessel 1 may also include an attached label 4 imprinted with an identifying bar code 7. Figures 1 and 5 show these additional features of the system.

Claim 9 and its dependents are directed to a toxicology specimen system (page 1, lines 8-14). Collection vessels 1 are configured to receive and contain a toxicology specimen, and wireless electronic memory tags 3 are attached to the vessels (page 10, line 26 – page 11, line 2). The wireless tags 3 remain attached to the vessels 1 as they are transported. The tags 3 are for non-contact storage and retrieval of information and contain stored data including an encoded electronic signature of the donor of a toxicology specimen (page 10, lines 25-26). Claims 10-16 detail several additional features, and claim 17 recites several of those features in combination. Claim 38 is directed to the toxicology specimen collection vessel, including a tamper-indicating seal.

Additional embodiments of a toxicology specimen system are claimed that include a population of collection vessels 1. Each of the collection vessels 1 is configured to receive and contain a toxicology specimen and has a wireless electronic memory tag 3 attached for non-contact storage and retrieval of information. The memory tag 3 contains stored data including an encoded electronic signature of the donor of a toxicology specimen. The population of collection vessels includes a member at a vessel distribution facility, a member at a specimen collection facility, and a member at a specimen testing laboratory facility. Members of the population are transportable between the facilities, and the tag 3 is attached to the vessel 1 such that it remains attached to the vessel 1 as it is transported between facilities.

Claim 18 recites a method for electronically storing information on a diagnostic or toxicology specimen vessel 1 and remotely reading information from the vessel 1. The method includes providing a population of biomedical specimen vessels 1, as shown in Figure 4. (page

12, lines 17-18) Attached to each of the vessels 1 is a wireless electronic memory tag 3 (page 10, line 26 – page 11, line 2). The population of vessels 1 includes members located at and transportable between a vessel distribution facility, (Inherently, the vessel distribution facility is the place where the activities described at page 12, line 17 to page 13, line 2 take place. Since this passage says that the codes 7 are correlated and stored on a central computer database and "then supplied" to multiple specimen collection sites, there must be a vessel distribution facility where the correlation and storage takes place before the supplying (i.e. distribution) of the specimen containers to the specimen collection sites takes place.), a specimen collection facility (page 8, lines 21-22), and a specimen testing laboratory facility (page 9, lines 7-9). The method further includes storing data on one of the memory tags 3 at the vessel distribution facility (inherently, the place where the activities described at page 12, line 17 to page 13, line 2 take place), shipping or distributing population members with the stored data from the distribution facility to the collection facility (page 12, line 24 – page 13, line 1), and reading the stored information from the electronic memory tag 3 with a non-contact electronic reader or scanner at a specimen testing laboratory facility (page 13, lines 15-22). The memory tags 3 remain attached to the vessels during the shipping or distributing.

Claim 19 recites a method involving collecting specimens in the recited vessels and storing information about the specimen and its donor.

Claim 42 recites the population of vessels for collecting toxicology specimens, with some members of the population at the vessel distribution facility, some at a collection facility and some at a testing laboratory. Claim 43 recites a similar population of biomedical specimen collection vessels.

Claim 44 covers either type of specimen collection and details procedures involved in the specimen collection phase.

In an embodiment, the method that is depicted in the flow chart labeled Figure 4 of the application includes collecting a specimen from a donor in the specimen container at the collection facility, and storing information about the specimen, donor, and/or tests to be performed on the specimen on the memory tags 3. The method may also include collecting and storing the electronic signature of the specimen donor on the electronic memory tag at the specimen collection facility.

Use of the invention provides numerous advantages. These include improved reliability in record handling, since there reliance on human data input is reduced. The shipping cost of the sample-filled vessels is reduced because they no longer need to be packaged with paperwork. The reference laboratory pickup of the vessels is more efficient, since linked computers of the specimen collection facility and specimen testing laboratory facility can be programmed to provide couriers with up-to-date routing information to make stops only at specimen collection facilities where specimens are ready for pick-up. The laboratory facility can enjoy further efficiency gains from being able to scan an incoming load of specimen vessels almost instantaneously and then be able to schedule the required testing stations, personnel or reagents for the respective tests needed on the specimens in the received load. This, in turn, allows the tests to be completed more quickly, so that the test results can be available more quickly. Perhaps in some medical situations, lives can be saved by this faster turn-around.

In the field of toxicology testing, the all-important chain of custody is made more reliable, since the identity of the specimen donor remains in the database, linked to the adhered wireless electronic memory tag.

As required by the Notices of Non-Compliant Appeal Brief the independent claims on appeal are "mapped" to the specification by page and line number or paragraph number and/or drawings as follows:

1. A diagnostic specimen system comprising

a population of biomedical specimen collection vessels (Figure 1, item 1) (page 8, lines 16-17 and 21 and page 9 lines 1-9) located at and transportable between a vessel distribution facility (inherently, the place where the activities described at page 12, line 17 to page 13, line 2 take place), a specimen collection facility (Figure 5, item 28) (page 12, line 21 – page 13, line 2), and a specimen testing laboratory facility (Figure 5, item 31) (page 14, lines 17-19),

wherein each of the collection vessels includes a wireless electronic memory tag (Figure 3) (page 11, lines 1-2) for non-contact storage and retrieval of information attached thereto such that the tag remains attached to the vessel (Figure 1, item 3) as the vessel is transported between facilities.

8. A diagnostic specimen system comprising:

a population of collection vessels located at and transportable between a vessel distribution facility (inherently, the place where the activities described at page 12, line 17 to page 13, line 2 take place), a specimen collection facility (Figure 5, item 28) (page 12 line 21 – page 13, line 2), and a specimen testing laboratory facility (Figure 5, item 31) (page 14, lines 17-19), wherein each of the collection vessels includes a wireless electronic memory tag (Figure 5) (page 11, lines 1-2) for non-contact storage and retrieval of information attached thereto such that the tag remains attached to the vessel (Figure 1, item 3) as the vessel is transported between facilities;

data stored on an electronic memory tag including an identification code for the vessel (Figure 4, item 11), the identity of the supplier of the vessel (Page 11, line 2) and product information about the vessel (Page 11, line 2), identifying information about a specimen contained in the vessel and about the specimen donor (Page 11, lines 4-5), and definition of the analytical tests to be performed on the specimen in the vessel (Page 11, lines 5-6); and

a label imprinted with an identifying bar code (Figure 2, item 7) attached to each vessel.

9. A toxicology specimen system comprising a population of collection vessels (page 8, lines 16-17 and 21, and page 9, lines 8-9) (Figure 5, items 27, 28 & 31),

each configured to receive and contain a toxicology specimen (page 1, lines 8-14) and having a wireless electronic memory tag (Figure 3) (page 11, lines 1-4) attached to the vessel for non-contact storage and retrieval of information, wherein the population includes members located at and transportable between a vessel distribution facility (inherently, the place where the activities described at page 12, line 17 to page 13, line 2 take place), a specimen collection facility (page 8, line 21), and a specimen testing laboratory (page 8, lines 8-9) (Figure 5, items 27, 28 & 31),

wherein each of the collection vessels includes a wireless electronic memory tag (page 11, lines 1-2) for non-contact storage and retrieval of information attached thereto such that the tag remains attached to the vessel as the vessel is transported between facilities (Figure 3).

17. A toxicology specimen system (Page 2, lines 16-17) comprising:

a population of biomedical specimen collection vessels, wherein the population includes members located at and transportable between a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory facility (Figure 5, items 27, 28 & 31),

each vessel having a wireless electronic memory tag attached to the vessel such that the tag remains attached to the vessel as the vessel is transported between facilities (Figure 3),

the electronic memory tag including a radio frequency transponder for non-contact storage and retrieval of information (Page 11, lines 13-21);

data stored on the electronic memory tags including an identification code for the vessel (Figure 4, item 11), the identity of the supplier of the vessel (Page 11, line 2) and product information about the vessel (Page 11, line 2), identifying information about a specimen contained in the vessel and about the specimen donor (Page 11, lines 4-5), definition of the analytical tests to be performed on the specimen in the vessel (Page 11, lines 5-6), and an encoded electronic signature of the donor of the toxicology specimen in the vessel (Page 13, line 24 – page 14, line 1); and

a label imprinted with an identifying bar code attached to each vessel (Figure 2, item 7).

18. A method for electronically storing information on a diagnostic or toxicology specimen vessel and remotely reading information from the vessel comprising:

providing a population of biomedical specimen vessels (page 8, lines 16-17 and 21 and page 9, lines 8-9), each having a wireless electronic memory tag attached thereto (page 1, lines 8-14), wherein the population includes members located at and transportable between a vessel distribution facility (inherently, the place where the activities described at page 12, line 17 to

page 13, line 2 take place), a specimen collection facility (page 8, line 21), and a specimen testing laboratory facility (Figure 5, items 27, 28 & 31) (page 8, lines 8-9);

electronically storing data on one of the electronic memory tags at the vessel distribution facility (inherently, the place where the activities described at page 12, line 17 to page 13, line 2 take place);

shipping members including the electronic memory tags attached thereto with electronically stored data from the vessel distribution facility to the specimen collection facility (inherently, the place where the activities described at page 12, line 17 to page 13, line 2 take place); and

reading the stored information from the electronic memory tag with a non-contact electronic reader or scanner at a specimen testing laboratory facility (page 14, lines 17-19) (Figure 4, item 21).

19. A method for recording information about a diagnostic or toxicology specimen on a diagnostic or toxicology specimen vessel comprising:

providing a population of biomedical specimen vessels (page 8, lines 16-17, and 21 and page 9, lines 8-9), each having a wireless electronic memory tag attached to the vessel at a vessel distribution facility (inherently, the place where the activities described at page 12, line 17 to page 13, line 2 take place);

distributing population members including the wireless electronic memory tag attached thereto to a specimen collection facility (Figure 4, item 13) (page 12, line 21 – page 13, line 2);

collecting a specimen from a donor in the specimen container at the specimen collection facility (Figure 4, item 14) (page 13, lines 3-4); and

electronically storing information about the specimen, donor, and/or tests to be performed on the specimen on the electronic memory tag (Page 11, lines 2-7).

38. A toxicology specimen system (Page 2, lines 16-17) comprising

a collection vessel (Figure 1) configured to receive and contain a toxicology specimen (Page 2, lines 16-17),

a tamper-indicating seal (Page 11, lines 10-12), and wireless electronic memory tag attached to the vessel such that the tag remains attached to the vessel as the vessel is transported (Figure 1, item 3), the tag for non-contact storage and retrieval of information and wherein the electronic memory tag contains stored data including an encoded electronic signature of the donor of a toxicology specimen (Page 13, line 24 – page 14, line 1).

42. A toxicology specimen system (Page 2, lines 16-17) comprising

a population of collection vessels (Figure 4, item 10), each configured to receive and contain a toxicology specimen and having a wireless electronic memory tag attached to the vessel for non-contact storage and retrieval of information (Page 11, lines 13-21),

the memory tag containing stored data including an encoded electronic signature of the donor of a toxicology specimen (Page 13, line 24 – page 14, line 1),

wherein the population includes a member at a vessel distribution facility, a member at a specimen collection facility, and a member at a specimen testing laboratory facility and wherein the members are transportable between the facilities and the tag is attached to the vessel such that

it remains attached to the vessel as the vessel is transported between facilities (Figure 5, items 27, 28 & 31).

43. A toxicology specimen system (Page 2, lines 16-17) comprising:

a biomedical specimen collection vessel and a tamper-indicating, wireless electronic memory tag (Page 11, lines 10-12) attached to the vessel such that the tag remains attached to the vessel as the vessel is shipped to between a between a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory facility (Figure 5, items 27, 28 & 31), the tag including a radio frequency transponder for non-contact storage and retrieval of information (Page 11, lines 13-21);

data stored on the electronic memory tag including an identification code for the container (Figure 4, item 11), the identity of the supplier of the vessel (Page 11, line 2) and product information about the vessel (Page 11, line 2), identifying information about a specimen contained in the vessel and about the specimen donor (Page 11, lines 4-5), definition of the analytical tests to be performed on the specimen in the vessel (Page 11, lines 5-6), and an encoded electronic signature of the donor of the toxicology specimen in the vessel (Page 13, line 24 – page 14, line 1); and

a label imprinted with an identifying bar code (Figure 2, item 7).

44. A method for recording information about a diagnostic or toxicology specimen on a diagnostic or toxicology specimen vessel (Page 2, lines 16-17) comprising:

providing a population of biomedical specimen vessels, each having a wireless electronic memory tag attached to the vessel, wherein the population includes a member at a vessel

distribution facility (inherently, the place where the activities described at page 12, line 17 to page 13, line 2 take place), a member at a specimen collection facility (Figure 5, item 28), and a member at a specimen testing laboratory facility (Figure 5, item 31), and wherein each of the vessels includes a wireless electronic memory tag (Figure 3) attached thereto such that the tag remains attached to the vessel as the vessel (Figure 1, item 3) is transported between facilities;

collecting a specimen from a donor in the specimen vessel at the specimen collection facility (Figure 4, item 14);

electronically storing information about the specimen, donor, and/or tests to be performed on the specimen on the electronic memory tag (Page 11, lines 2-7); and

collecting and storing the electronic signature of the specimen donor on the electronic memory tag at the specimen collection facility (Page 13, line 24 – page 14, line 1).

6. Grounds of Rejection to be Reviewed on Appeal

The following rejections are appealed:

A. Whether Claims 1-21 and 40-44 are indefinite under 35 U.S.C. 112, second paragraph.

B. Whether Claims 1-4, 6-7, 9-12, 14-15, 19, 21, 38, 40-41, and 44 are anticipated by U.S. Patent No. 6,535,129 to Petrick ("Petrick") under 35 U.S.C. 102(e).

C. Whether Claims 1, 6-7, 9, 14-15, 19, 21, 40-41 and 44 are anticipated under 35 U.S.C. 102(b) by U.S. Patent No. 5,777,303 to Berney ("Berney").

D. Whether Claim 21 is unpatentable under 35 U.S.C. 103(a) over Berney.

E. Whether Claims 5, 8, 13 and 18 are unpatentable under 35 U.S.C. 103(a) over Petrick or Berney in view of U.S. Patent No. 5,314,421 to Leuenberger ("Leuenberger").

F. Whether Claims 16-17, 20, 42, and 43 are unpatentable under 35 U.S.C. 103(a) over Petrick or Berney in view of U.S. Patent No. 5,613,012 to Hoffman et al. ("Hoffman") or U.S. Patent No. 5,948,103 to Fukuzaki ("Fukuzaki").

G. Whether Claims 2 and 10 are unpatentable under 35 U.S.C. 103(a) over Berney in view of disclosure of RD 421048 A ("RD 421048 A").

H. Whether Claims 3-4 and 11-12 are unpatentable under 35 U.S.C. 103(a) over Berney in view of EP 1,004,359 A2 to Stevens et al. ("Stevens").

I. Whether Claim 38 is unpatentable under 35 U.S.C. 103(a) over Berney in view of U.S. Patent No. 5,135,313 to Bowman ("Bowman").

J. Whether Claim 8 is unpatentable under 35 U.S.C. 103(a) over Berney, RD 421048 A, Stevens and Leuenberger.

K. Whether Claim 17 is unpatentable under 35 U.S.C. 103(a) over Berney, RD 421048 A, Stevens, Leuenberger and Hoffman or Fukuzaki.

7. Arguments

A. Claims 1-21 and 40-44 Are Not Indefinite.

The Examiner rejected Claims 1-21 and 40-44 as indefinite incorrectly asserting that they are not directed to statutory subject matter.[1] The Examiner also rejected Appellant's claims as indefinite, asserting that certain of Appellant's claim limitations do not recite a particular structure, and so do not limit the scope of its claims.[2] Then, the Examiner concluded that, since some of Appellant's claim limitations are not directed to specimen collection vessels, those limitations rendered claims to a larger specimen system indefinite, so the Examiner disregarded the limitations.[3] Finally, the Examiner also erroneously concluded that Claim 18 of Appellant's application was indefinite.

According to the Administrative Procedure Act, a PTO Board must "hold unlawful and set aside agency actions, findings, and conclusions found to be...arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." Thus, a patent examiner must abide by the law that a patent may be obtained for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, subject to the conditions of [Title 35 of the United States Code]".[4] These four categories of subject matter eligible for protection are meant to capture anything under the sun made by man.[5] A "manufacture" has

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[1] Paragraph 3 of Office Action mailed January 10, 2006. ("According to 35 U.S.C. 101, patentable inventions are related to 'any new and useful process, machine, manufacture, or composition'. It is not clear, which category of this four the claimed subject matter belongs to.").

[2] Id. ("*Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a* ***particular structure*** *does not limit the scope of a claim or claim limitation.*").

[3] Id. ("The examiner concludes that since the location of the vessels does not further limit their structure, the limitation recited in the independent claims after 'wherein' (excluding the structural elements related to the vessels themselves) does not bear any patentable weight.")

[4] 35 U. S. C. 101.

[5] *Diamond v. Chakrabarty* 447 U.S. 303, 309, 206 USPQ 193, 197 (1980).

been described as any man made item not found in substantially the same form in nature that is neither a machine nor a composition of matter.[6] An applicant having an invention falling into one of the categories of eligible subject matter must state the subject matter it regards as its invention with a reasonable degree of clarity and particularity.[7] In doing so, the "[a]pplicant may use functional language, alternative expressions, negative limitations, or any style of expression or format that makes clear the boundaries of the subject matter for which protection is sought."[8] Indeed, patent examiners "should *not* reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirements."[9]

To find, as the Examiner has done, that Appellant's claims are indefinite under 35 U.S.C. 112, second paragraph, because "[i]t is not clear, which category of [the four delineated in 35 U.S.C. 101] the claimed subject matter belongs to,"[10] is not in accordance with the law. In fact, according to MPEP § 2106,[11] a "manufacture" is "the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand labor or by machinery." Certainly, a specimen system having collection vessels in specified locations is a manufacture. To find otherwise, as the Examiner has done, requires some reasoned explanation, but the Examiner merely concludes that "[l]ocation of the [Appellant's claimed] vessels is not a manufacture" without explaining how Appellant's claims

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[6] 1 DONALD S. CHISUM, *Chisum on Patents* § 1.02[3] (2006) discussing 1 W. Robinson, *The Law of Patents for Useful Inventions* 270 (1890).

[7] MPEP 2173.02.

[8] MPEP 2173.01.

[9] MPEP 2173.02 (emphasis added).

[10] Paragraph 3 of Office Action mailed January 10, 2006.

[11] The Examiner cited MPEP 2106 in paragraph 3 of Office Action mailed January 10, 2006.

fail to describe man made items.[12] The Examiner feels that claiming a specimen container supplier, a specimen collection site, and a laboratory "would hardly have any statutory basis", even though such a claim would indeed fall within the definition of a manufacture provided by MPEP § 2106.[13] Thus, the Examiner misunderstands the law,[14] and did not act in accordance with the law. Appellant's claims are not indefinite under 35 U.S.C. 112, second paragraph, for allegedly failing to describe statutory subject matter under 35 U.S.C. 101. Appellant may claim a manufacture under 35 U.S.C. 101 and doing so does not render such claims indefinite under 35 U.S.C. 112, second paragraph.

The Examiner also insisted that each of Appellant's claims 1-20 and 40-44 was indefinite under 35 U.S.C. 112, second paragraph, saying, "It is not apparent what particular structure of the diagnostic specimen system is recited in the claims, besides a particular structure cited for collection vessels. Location of a part of the system at a specific place cannot be considered 'a particular structure' of the diagnostic system."[15] Patent claims, however, frequently recite elements in various positions, and those positions are attributes of the elements that are given weight in the evaluation of patentability. Literally thousands of issued U.S. patents employ the term "located at" or some very similar variation thereof in their claims to describe the subject matter protected. Furthermore, failing to recite a particular structure does not in and of itself render a claim indefinite. An applicant certainly may use clear functional language to define the

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[12] Paragraph 18 of Office Action mailed January 10, 2006, Rejections under 112, second paragraph.

[13] Id.

[14] The Examiner repeatedly confounded the meaning of 35 U.S.C. 112, second paragraph. For another example, she questioned whether Appellant's system "belongs to the claimed subject matter of the instant application." Paragraph 2 of Office Action mailed January 10, 2006.

[15] Paragraph 3 of Office Action mailed January 10, 2006 (emphasis added).

scope of protection sought.[16] So the Examiner is wrong to assume that an applicant's claims must recite a particular structure, and she is wrong again to say that Appellant's claims do not. Appellant may use the term "located at" to describe the subject matter it regards as its invention.

The Examiner also found that:

> [I]t is not clear, what will happen to the subject matter of the claim, if a part of the system, after being located at the specified location for some time, will be on the way to a different location (e.g. disposal), or on the way from the manufacturing site. Also, it is not clear if the diagnostic system manufactured at the manufacturing site and still located at that site belongs to the claimed subject matter of the instant application. Furthermore, it is not clear, if the same vessels should always be present at these particular locations, or these vessels are moving from one place to another? <u>If the vessels are moving and changing their location, how can such a system be definite?</u>[17]

Thus, it appears that the Examiner imposed a requirement that Appellant's claims must describe a static system. The Examiner pointed to no authority supporting such a requirement, nor does any exist. In fact, definiteness does not preclude the inclusion of moving claim elements. The Examiner wonders "how the scope of the claims and the patentability of the claimed subject matter as a whole can be time variable" and questions whether "the patent becomes invalid ['when the whole batch of the vessel is transported from one specific location to

[16] MPEP 2173.01.

[17] Paragraph 3 of Office Action mailed January 10, 2006 (emphasis added).

another specific location.']"[18] To answer the Examiner, Appellant claims systems having limitations stated by its claim language. Whether the claims would become invalid is not at issue under 35 U.S.C. 112, second paragraph. Appellant's claimed systems may have moving elements, and the Examiner was wrong to reject the claims as indefinite for doing so.

The Examiner went on to find that "the vessel distribution facility (shelves with the vessels), the specimen collection facility (a special restricted area in the laboratory) and the specimen testing laboratory can be the same place'' and "[concluded] that since the location of the vessels does not further limit their structure, the limitation recited in the independent claims after 'wherein' (excluding the structural elements related to the vessels themselves) does not bear any patentable weight."[19] Actually, the Examiner is correct in observing that the facilities can be very close, but that does not render the Appellant's claims indefinite under 35 U.S.C. 112, second paragraph. Also, Appellant may specify limitations on its system that do limit the structure of its collection vessels. To assert that every limitation on Appellant's system must be directed to its specimen vessels is imposing a requirement that is not in accordance with the law, and the Examiner pointed to no supporting authority. Appellant may claim elements at specified locations, even if those locations can be in close proximity to one another, and Appellant is free to specify limitations on its specimen collection system that limit its system beyond the structure of its collection vessels.

Finally, the Examiner concluded that Appellant's Claim 18 "is indefinite as to which data are stored at the vessel distribution facility."[20] However, claiming "data" as an element of a

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[18] Paragraph 13 of Office Action mailed January 10, 2006, Rejections under 112, second paragraph.

[19] Id.

[20] Id.

system does not render the claim indefinite under 35 U.S.C. 112, second paragraph, despite the Examiner's protestations. Definiteness does not require Appellant to specify the particular kind of data stored on its electronic memory tags, so the Examiner was wrong again when she rejected Appellant's Claim 18 as indefinite for claiming data.

Definiteness of claim language under 35 U.S.C. 112 is analyzed in light of the content of the particular application disclosure, the teachings of the prior art, and the claim interpretation that would be given by one of ordinary skill in the art at the time of the invention.[21] Potential infringers need to be apprised of the scope of patent protection defined by a patent's claims, and they would have no problem with Appellant's claims in that regard.

Figure 5 of Appellant's application illustrates, schematically, a specimen container supplier, a specimen collection site, and a laboratory. One of ordinary skill would understand that Appellant claims a system that includes a population of vessels. The vessels are at specified facilities and the vessels are *transportable* between the facilities, and in some claims, the vessels are transported between the facilities. Appellant's claims are not indefinite for failing to describe statutory subject matter. Nor are Appellant's claims indefinite for claiming data, or for limiting claim elements to specified locations. Therefore, the Examiner's rejections of Claims 1-20 and 40-44 as indefinite should be reversed.

B. Claims 1-4, 6-7, 9-12, 14-15, 19, 21, 38, 40-41, and 44 Are Not Anticipated by Petrick.

The Patent Office accorded Appellant a filing date of December 14, 2000 for the application that is the subject of this Appeal. After several official exchanges between the Examiner and Appellant, an Office Action mailed January 15, 2004, rejected claims of the application for the first time under 35 U.S.C. 102(e) over U.S. Patent 6,535,129 to Petrick, which

[21] MPEP 2173.02.

issued March 18, 2003 on an application filed November 17, 2000. Appellant submitted Rule 1.131 declarations of co-inventors Jason Bowman, Danny Charles Bowman and David Michael Lewis showing invention of the claimed subject matter antedating the filing date of Petrick to remove the reference as prior art.[22]

The examiner found no fault in the proof that applicant antedates Petrick. Instead, she "indicate[d] that [Appellant's and Petrick's] inventions are the same"[23] because, she asserted, Appellant's specification and Petrick's patent disclose common elements.[24] The Examiner found that, since both Appellant and Petrick disclose specimen vessels and business forms,[25] Appellant's application is claiming the same patentable invention as Petrick's patent.[26] Then, she "[took] into account a very short difference in the filing dates of the application and the patent" and ruled that "[Appellant's] Declaration under 1.131 is not valid in this case."[27]

37 CFR 41.203(a) (revised from 37 CFR 1.601(a)) states the general rule for determining whether an application is claiming the same patentable invention as a patent thusly:

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[22] Appellant first responded June 15, 2004 to the Office Action mailed January 15, 2004. The Patent Office then issued a Notice of Non-Compliant Amendment July 6, 2004, to which Appellant responded July 9, 2004. Appellant later also submitted a Supplemental Response to the June 15, 2004 Office Action on July 23, 2004. The declarations swearing behind Petrick are contained in these three submissions following the June 15, 2004 Office Action.

[23] Paragraph 18 of Office Action mailed January 10, 2006, Regarding Applicant' patentable invention *vs.* Petrick's US 6,535,129.

[24] Id.

[25] Id. The Examiner apparently asserted that Petrick's business form and Appellant's wireless electronic memory tag are one and the same with her statement that "...Applicants claim a population of vessels with attached business forms (the wireless electronic memory tag)." This is so even though the Examiner's version of "the same patentable invention" analysis reads features disclosed in Petrick's specification into its claims. Thus, under her analysis, Petrick's business form should resemble one of the paper versions disclosed in Petrick's specification at Figs. 3a and 3b, rather than the wireless electronic memory tag claimed by Appellant. So, her "same patentable invention" analysis improperly reads limitations into the claims and she appears to have inconsistently applied her own improper analysis.

[26] Paragraph 18 of Office Action mailed January 10, 2006, Regarding Applicant' patentable invention *vs.* Petrick's US 6,535,129.

> *Interfering subject matter.* An interference exists if the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing part and vice versa.

The predecessor of the Court of Appeals for the Federal Circuit held in *In re Eickmeyer*[28] that the PTO cannot deny an applicant an interference on the grounds that the applicant and a patentee are not interfering in fact and also deny the applicant the opportunity to swear behind the patent on the grounds that the applicant is claiming the same invention as the patentee. Accordingly, since an interference-in-fact requires a two-way analysis of the "same patentable invention" set forth in rule 41.203(a), such must also apply to the interpretation of Rule 1.131.

The Trial Section of the Interferences Division of the Board of Patent Appeals and Interferences in *Winter v. Fujita*[29] set forth a two-way analysis to determine the existence of an interference-in-fact. The Court of Appeals for the Federal Circuit uses the same test. *Medichem S.A. v. Rolabo S.L.,* 77 USPQ 2d 1865 (Fed. Cir. 2006). In the first step of the analysis, the claimed invention of Petrick is presumed to be prior art to the applicant. If Appellant's claim is new and non-obvious in view of Petrick's claim, the claims describe separate patentable inventions. If not, the second step is undertaken in which Appellant's claim is presumed to be prior art to Petrick's, and the obviousness analysis is performed. If Petrick's claim is new and non-obvious in view of Appellant's claim, the claims describe separate patentable inventions. The claims describe the same patentable inventions only if Petrick's claimed invention

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[27] Id.

[28] 602 F.2d 674, 202 U.S.P.Q. 655 (CCPA 1979).

[29] 53 USPQ2d 1234, 1243 (1999), reh'g denied, 53 USPQ2d 1478 (BPAI 2000).

anticipates or renders obvious Appellant's claimed invention *and* vice versa.[30] The analysis refers only to the parties' claims, not the remainder of the specifications.

B.1. Evaluation of Applicant's System Claims 1-17 and 40-43

Petrick's Claims 1 and 7 read:

> 1. A business form comprising:
>
> a first portion providing chain of custody information therein; and
>
> a second portion linking said form with at least one specimen;
>
> wherein said business form further includes a wireless identification device associated therewith that electronically provides at least an identifier in response to a query for automatically establishing the chain of custody of said specimen, said wireless identification device being associated with the form such that de-associating the device from the form results in at least partial destruction of the form in a manner that is readily seen through visual inspection of the form.
>
> 7. The business form of Claim 1 wherein said wireless identification device is adhered directly to the specimen or to a container containing the specimen.

And Appellant's Claim 1 states:

> A diagnostic specimen system comprising a population of biomedical specimen collection vessels located at and transportable between a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory facility, wherein each of the collection vessels includes a wireless electronic memory tag for non-contact storage and retrieval of information attached thereto such that the tag remains attached to the vessel as the vessel is transported between facilities.

B.1.(a) Assuming Petrick is Prior Art to Appellant for 41.203(a)Test

Assuming Petrick's claim is prior art, Appellant's claim is novel. Appellant's claim describes a diagnostic specimen system including a population of collection vessels having

[30] Id.

members at specified locations. Petrick's claim does not disclose multiple vessels at the specified locations. Appellant's claim is therefore new in view of Petrick's claimed invention.

Appellant's diagnostic specimen system is also not an obvious variation of Petrick's business form. Nothing in Petrick's claim teaches or suggests the vessels at various locations set forth in Appellant's claim. Thus, Appellant's claim is not an obvious variation. Appellant's claim is not even directed to similar subject matter. Petrick claims a business form; Appellant claims a system comprising a population of vessels. Petrick's wireless identification device (WID) is attached to the form - - not the specimen collection vessel. Petrick's Figure 3B embodiment discussed at column 5, lines 19-36 (and her claim 7) suggests removing the wireless identification device from the form as part of a label used to seal the vessel. But that still completely omits vessels with the tags at the vessel distribution facility, since the seal is not added until the specimen has been collected. Since Petrick emphasized the importance of keeping the tag with the form, (at least until conspicuous removal takes place), it would not have been obvious to put the tag on at the vessel distribution facility. Therefore, Appellant is not claiming the same patentable invention as Petrick's Claim 1 or 7.

B.1.(b) Assuming Appellant Is Prior Art to Petrick for 41.203(a) Test

If Appellant's claim is assumed to be prior art to Petrick's, the same result obtains. Petrick's claim requires a new business form having two portions and a particular association between the business form and the wireless identification device. Appellant's claim does not disclose or suggest a business form (much less one having two portions) or any particular

relationship between such a form and an identification device.[31] Thus, Petrick's claim is non-obvious in view of Appellant's claim, so under *Winter* the inventions are separately patentable.

Even if the Board eschews *Winter* and risks violating the rule of *Eickmeyer* by applying the test as one-way only, applicant is not claiming the same invention as Petrick. Appellant's claim is new and non-obvious when Petrick's claim is presumed to be prior art.

B.2. Evaluation of Appellant's Method Claims 18-21 and 44

Petrick's Claim 8 recites:

> A method of establishing a chain of custody comprising:
> associating a business form and a radio frequency identification device with at least one object, said wireless identification device being associated with the form such that de-associating the device from the form results in at least partial destruction of the form in a manner that is readily seen through visual inspection of the form; and
> using both the business form and the radio frequency identification device in combination to establish a chain of custody for the object including querying said device and receiving a response that is automatically used to establish said chain of custody.

And Appellant's Claim 18 reads:

> A method for electronically storing information on a diagnostic or toxicology specimen vessel and remotely reading information from the vessel comprising:
> providing a population of biomedical specimen vessels, each having a wireless electronic memory tag attached thereto, wherein the population includes members located at and transportable between a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory facility;
> electronically storing data on one of the electronic memory tags at the vessel distribution facility;

[31] This is so although Appellant's claim is broad enough to be infringed by a device having the features described by Petrick's claim. While some embodiments of Petrick could be implemented to infringe Claim 1, and *vice versa*, such infringements are not inevitable. If a practitioner of Appellant's Claim 1 does not use a business form, Petrick is not infringed. If a practitioner of Petrick does not have containers at the locations of Appellant's Claim 1, Appellant's Claim 1 is not infringed.

shipping members including the electronic memory tags attached thereto with electronically stored data from the vessel distribution facility to the specimen collection facility; and

reading the stored information from the electronic memory tag with a non-contact electronic reader or scanner at a specimen testing laboratory facility.

B.2.(a) Assuming Petrick Is Prior Art to Appellant for 41.203(a)Test

The Examiner asserts that Appellant's Claim 18 and Petrick's Claim 8 claim the same patentable invention, but Petrick's claim does not teach or suggest Appellant's "providing a population of biomedical specimen collection vessels" at Appellant's claimed facilities. Nor does Petrick teach or suggest storing data at a vessel distribution facility. Petrick's discussion of its Fig. 3B teaches away from putting data or the specimen vessel at a vessel distribution facility, since adhering the seal in Petrick is intended to apply the RFID tag at the same time. Nor does Petrick's claim teach or suggest Appellant's Claim 19, or collecting and storing an electronic signature, as do Appellant's Claim 20 and 44. So, Appellant's Claims 18-21 and 44 are both new and non-obvious in view of Petrick's Claim 8.

B.2.(b) Assuming Appellant Is Prior Art to Petrick for 41.203(a)Test

Neither of Appellant's Claims 18-21 or 44 teach or suggest the business form or Petrick's claimed particular association between Petrick's business form and its radio frequency identification device. So, Petrick's Claim 8 is new and non-obvious, and Appellant is not claiming the same patentable invention as the patent.

The Examiner insists that Appellant and Petrick claim the same patentable invention without showing that Petrick's claims anticipate or render Appellant's claims obvious. No doubt the Examiner has not done so because the task is impossible: Appellant is not claiming the same patentable invention as Petrick. Appellant can properly swear behind Petrick, so the rejections of Appellant's claims using Petrick as prior art should be reversed.

B.3. Appellant's Application and Petrick Are Classified in Unrelated Classes.

The PTO often asserts that inventions are patentably distinct and supportive of two patents in making restriction requirements. According to MPEP Section 808.02 separate classifications is a reason for insisting on restriction of distinct inventions. Petrick is classified in U.S. Class 340/572.1, relating to electrical communications, completely unrelated to electrical communications is U.S. Class 436/56, where applicant's published application has been classified.[32] The PTO first classified Appellant's application in a separate class from that in which Petrick's patent is classified, establishing that the inventions are independent and distinct. MPEP § 2301.03 points out that claims that are patentably distinct, they are not interfering. The examiner now erroneously finds that the application and the patent are claiming the same patentable invention.

B.4. The Examiner's Comments Illuminate Her Errors

In Section 18 of the January 10, 2006, Office Action, the Examiner responds to Applicants' arguments. In the paragraph bridging pages 13 and 14, the Examiner says that the Applicants' make a statement that the Examiner does not quite understand, referring to Applicants' argument that if Applicant's claim is new and not obvious in view of Petrick's claim, the claims describe separate patentable inventions. The Examiner's stated misunderstanding highlights her legal error. In order to determine whether two applicants claim the same patentable invention, one must focus on the claims. That is what the rules say, that is what the Board and court say, but that is not what the Examiner did.

[32] To this point, the Examiner replies that Appellant's application contains both system and method claims, yet was not restricted. The relevance of this fact is left unexplained. Paragraph 18 of Office Action mailed January 10, 2006, Regarding Applicant' patentable invention *vs.* Petrick's US 6,535,129.

The Examiner goes on to say "[I]t appears that there is no case when the applicant's and Petrick's inventions can be the same." In this respect, the Examiner is correct, but unfortunately, the Examiner did not rely on this observation. Instead, she goes on to say that inventions are the same because Petrick claims a business form comprising a wireless electronic memory tag attached to a vessel (Claim 7), while the applicant's claim a population of vessels with attached business forms (the wireless electronic memory tag). This analysis is erroneous because it ignores material limitations of the claims. Petrick's claim 1 is to a business form with a first portion providing a chain of custody information and a second portion linking the form with a specimen. Further, the business form includes the wireless identification device such that disassociating the device from the form results in at least a partial destruction of the form in a manner that is readily seen through visual inspection of the form. Applicant's claim has nothing like that.

Applicant's claim 1 recites a population of biomedical specimen collection vessels located at and transportable between a vessel distribution facility, a specimen collection facility and a specimen testing laboratory facility. Petrick's claims 1 and/or 7 do not have populations of vessels at these various facilities. The Examiner asserts that the location of the claimed vessels does not bear patentable weight. As pointed out above, the examiner is wrong in that respect, and that may contribute to her error concerning whether or not applicant and Petrick are claiming the same patentable invention.

The Examiner goes on to discuss the recitation of the various locations in applicant's claim: "Moreover, contrary to applicants' statement, the vessels cannot be located at the specific locations all the time, because they are transported from one location to another, which destroys patentability of the population of vessels: if the whole group of vessels is transported from one

specific location to a different specific location, the patent would be invalid for the time period of their transportation." But, there is no requirement that the vessels be located in specific locations all the time. The law simply does not care one way or the other. The Examiner's statement that transporting the vessels destroys the patentability of the vessels and that the patent is invalid during the period of the transportation makes no sense. While it may be possible to consider certain combinations of vessels in various locations that do not infringe the claim, the fact that vessels may be situated at various locations cannot possibly invalidate the claims. However, such issues are simply irrelevant: as noted the claim is definite; the recitations are meaningful, and cannot give no patentable weight.

In the full paragraph on page 14, the Examiner addresses Applicants' statement that Applicants' claim does not disclose or suggest a business form like Petrick's. The Examiner responds to this by focusing on Applicants' specification, not properly restricting the focus to the words of Applicants' claims. As noted, it is the claims that are to be compared, not the specification. The examiner purports to be reading Applicants' claims in light of the specification, but instead she wholesale imports limitations from the specification into the claim. Essentially, what the Examiner has done in her "same patentable invention" analysis is to focus solely on the two specifications and ignore the fact that she is suppose to compare the claims.

The next paragraph of the Office Action further illustrates the Examiner's error. She asserts that she is reading Petrick's claim reciting the business form with the wireless electronic tag attached to the vessel in light of the specification. She concludes that any routineer in the art can conclude that this is the Applicant's population of vessels. How in the world one finds obvious the various locations claimed by Applicants' from the words of Petrick's claim is not enunciated. The Examiner makes no effort to make a showing of that.

In discussing claim 18, on page 15 of the Office Action, the Examiner asserts that Petrick's claim 8 essentially repeats Applicants' method of electronically storing information. Once again, the examiner is ignoring material limitations of Petrick's claim, including the limitations "said wireless identification device being associated with a form of such that de-associating the device from the form results in at least partial destruction of the form in a manner that is readily seen through visual inspection of the form." Applicants' claim has no such limitation.

In the final paragraph that section on page 15 of the Office Action, the Examiner argues that she did not have a responsibility to specify an interference count, because the application is not in a stage of interference. But then she asserts that applicants' invention is no different than Petrick's to deny Applicants' access to Rule 131 to swear behind Petrick. If that is the case, then under the rule of the *Eickmeyer* case, Applicant should be entitled to provoke an interference and the typical process is for the examiner to propose a count.

In the final two lines of this paragraph, the Examiner goes on to say "taking into account a very short difference in the filing dates of the application and the patent, the declaration under 1.131 is not valid." The Examiner makes no explanation as to why she deems the short difference in the filing dates to have any pertinence, and indeed it seems there is no possible explanation. Another examiner error.

C. Claims 1, 6-7, 9, 14-15, 19, 21, 40-41 and 44 Are Not Anticipated by Berney.

C.1. Claims 1, 6-7, 9, 14-15, 21, and 40-41 Are Not Anticipated by Berney.

Applicant's claimed invention relates to improvements in identification, logistics control, and information management for biomedical specimens collected for diagnostic or toxicology testing. Diagnostic and toxicology specimens are typically collected for analytical testing from

donors at collection sites such as hospitals, clinics, or doctors' offices. These specimens are collected in primary specimen containers specifically designed to completely and safely contain the specimens during handling and shipment in order to preserve the integrity of the specimens and to protect the health of persons who come in contact with the containers. In addition, primary toxicological specimen containers are typically provided with tamperproof locks or seals to ensure that the integrities of the toxicological specimens are not breached by unauthorized persons or by mishandling of the containers.

Successful testing requires the collection, recording, and maintenance of essential information about each diagnostic or toxicology specimen. Such information includes the identity and nature of each specimen, the identity of the specimen donor, the test or tests to be performed on the specimen, the identity of the person collecting the sample, the time and place of collection, and the results of tests performed on the specimen. Also, toxicology specimens typically require written authorizations signed by their donors. Because most specimen collection sites do not have testing laboratories on site, the specimens are typically sent to remote reference laboratories. Accordingly, the pertinent information about a particular specimen must be accurately communicated to the laboratory which tests the specimen, and the laboratory must in turn accurately report the test results for that specimen back to the site where the specimen was originally collected or to another remote site.

Prior to applicant's invention, the recording, maintenance, and communication of specimen and testing information was usually done using preprinted, duplicate-page forms having spaces for manually entering designated information onto the forms. Duplicate copies of the completed forms were used to communicate and record information among and between multiple departments or sites involved with the handling or testing of a specimen. The primary

specimen containers and copies of the associated forms were typically maintained together by placing them together in secondary containers such as boxes or sleeves. These secondary containers are then transported to a reference laboratory to conduct the required tests on the specimens.

Reliable, legal evidence linking the specimen to be tested to the donor is critical, particularly for toxicology specimens such as urine specimens to be tested for illicit drugs.

Because the specimens going to a particular laboratory originate from multiple remote collection sites, the collection and delivery of such specimens requires coordination between the collection sites, the laboratory, and a courier. Because many collection sites have only a sporadic need for diagnostic or toxicology testing, it is often inefficient for a designated courier to visit a potential collection site daily or semi-daily to possibly collect specimens for delivery. Avoiding such inefficiency requires collection to notify either the laboratory or a courier each time specimens are awaiting collection sites for delivery to the laboratory, causing a different type of inefficiency.

Reference laboratories typically included automated handling and testing equipment. Such laboratories had automated sorters and conveyors for routing specimens to testing stations and testing equipment that automatically performed the required tests on the specimens with minimal manual human intervention. Even such automated laboratories have needed to receive and inventor specimens from remote specimen collection sites by manually unpacking each specimen and the associated forms from their boxes or sleeves. Once testing had been performed on a specimen, a laboratory typically recorded the test results manually on the associated forms and then reported the test results by sending the completed forms to the originating specimen collection site or other selected destination.

Those methods for information management and logistical control for biological specimens collected for diagnostic or toxicology testing cause a number of difficulties. The use of written forms and written labels to record, maintain, and communicate specimen information is especially problematic. Manual entry of information onto forms or labels at collection sites and laboratories is labor intensive and causes delays in processing the specimens and information. Also, written forms or labels are sometimes illegible or became obliterated by handling or spills, causing a loss or miscommunication of essential information. Furthermore, it is necessary to physically maintain copies of the forms with the associated specimens. These forms added bulk to transport packaging for the specimen containers, and there is a risk of loss or dissociation from the specimens. In addition, the forms have to be individually handled and scanned or read when received by a reference laboratory, adding labor cost and causing delays that lead to underutilization of the automated laboratory handling and test equipment. Lost or dissociated forms could cause potentially harmful delays in the testing or reporting of diagnostic test results for distressed donors experiencing medical emergencies. In addition, if a form containing an authorization signature of a toxicology specimen donor was lost or misplaced, the test can not be performed until the donor again authorizes the test.

Bar codes did not eliminate the need for written forms to record and manage specimen information nor the associated problems. In addition, the bar codes on specimens and forms still required individual scanning and conveyed only limited basic identity information about the specimens.

Also, because independent specimen collection sites generated specimens only sporadically, the process of collecting specimens from these sites was problematic. Having couriers regularly visit sites having no specimens for collection wasted labor and transportation

costs. Alternatively, having the sites request collection on a case-by-case basis was also labor intensive and subject to communication delays or miscommunication.

Berney discloses a system for registering useful information during analyses of blood in conventional glass test tubes 1.[33] Berney's electronic memory labels 4 are attached to supports 31 that are fixed on the test tubes 1[34] in a testing laboratory at the time of sample analysis.[35] The supports 31 have spring like shape for attaching the test tubes[36] and rest on a base 33 including a bus system 46 for transferring information to and from the labels 4 during analysis.[37] Berney does not disclose and is not concerned with vessels at a vessel distribution facility or a specimen collection facility. Berney's spring-like supports 31 suggest to one of ordinary skill in the art a temporary affixation to a test tube. At column 2, lines 29-30, Berney's statement that these allow a firm fixation of the label 30 onto the test tube 32 at the time of analysis clearly suggest that affixation at that time is the only time of concern to Berney. In particular, a spring-loaded mount, which is obviously removable, does not suggest a chain of custody proof system.

Berney anticipates Appellant's claims only if each and every element as set forth in the claims is found either expressly or inherently described.[38] While she acknowledged that Berney does not expressly disclose Appellant's claimed inventions, the Examiner asserted that Berney

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[33] Col. 1, Line 11 of Berney.

[34] Col. 2, Lines 22-24 of Berney.

[35] Col. 1, Line 18; Col 1, Line 36; Col. 1, Lines 64-65; Col. 2, Line 29; Col. 3, Lines 18-25; Col. 4, Line 7 of Berney (Emphasis added).

[36] Col. 2, Lines 28-30 of Berney.

[37] Col 2, Lines 34-56, Figs. 3 and 4 of Berney.

[38] MPEP 2131 citing *Verdegaal Bros. v. Union Oil Co. of California* 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

inherently discloses Appellant's claimed population of biomedical specimen collection vessels.[39] But, to be inherent, the features of Appellant's claimed invention must *necessarily* be present in the Berney disclosure,[40] and Appellant's specified vessel locations are not even consistent with Berney's disclosure, much less, *necessarily present*. Berney's label provides a temporary mount to a test tube during analysis of the test tube contents in a laboratory; only one of the three facilities described by Appellant's claims. Thus, Berney does not inherently disclose any of Appellant's Claims 1, 6-7, 9, 14-15, 21 and 40-41. The Examiner's rejections of these claims should be reversed.

C.2. Claim 19 Is Not Anticipated by Berney.

Berney describes its process of performing blood analysis thusly:

> [F]irstly the reference data of the patient under concern and the kind and number of analyses to be performed are fed directly from a central data base into the label. Secondly the date of analysis, the used analysis apparatus, the name of the service operator, the result data, etc are registered. Finally all this information is transferred to the centralized data bank of the patient.[41]

Thus, Berney's labels are attached in the lab and one of ordinary skill would appreciate that the labels are also removed in the lab, so that the labels can be reused with another test tube after the information is transferred from them to a centralized data bank. There is no reason to attach electronic labels to Berney's test tubes prior to sample collection because Berney says reference data of the patient is not transferred to the labels until during the time of sample analysis.[42] Thus, Berney is concerned primarily with recording specimen analysis data, not

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[39] Paragraph 6 of Office Action dated January 10, 2006.

[40] MPEP 2112 (IV.).

[41] Col. 3, Lines 18-25.

[42] The Examiner argues at Paragraph 18 of the Office Action mailed January 10, 2006, Regarding anticipatory rejections over Berney under 102(b) that "[t]here is no way [Berney's] tag can be attached to the test tube *after* the collected sample was transported to the lab," but this assertion ignores the fact that Berney's test tube can be

complete chain of custody information, so Berney does not disclose electronic memory tags attached to vessels at a distribution facility, or distributing vessels having electronic memory tags to a collection facility. Therefore, Berney does not anticipate Appellant's Claim 19, and the Examiner's rejection of the claim should be reversed.

C.3. Claim 44 Is Not Anticipated by Berney.

Berney does not disclose collecting and storing the electronic signature of a specimen donor on an electronic memory tag at a specimen collection facility. Berney does not even disclose collecting an electronic signature, much less collecting and storing one at a collection facility. So Berney does not anticipate Appellant's Claim 44, and the Examiner's rejection of the claim should be reversed.

D. Claim 21 Is Patentable over Berney.

Although the Examiner rejected Claim 21 as anticipated by Berney, she also acknowledged that Berney does not disclose transporting vessels to a specimen-testing laboratory. But, she reasons, since transporting vessels is conventional medical practice, one of ordinary skill would have transported Berney's vessels, "because it allows tracking the vessels using Berney's inventive electronic tags on the specimen vessels."

An obviousness rejection based on a single prior art reference, however, must include evidence showing a suggestion or motivation to modify the reference to produce the allegedly obvious invention.[43] Subjective belief and unknown authority are not proper substitutes for

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associated with a patient at the time of sample collection by means other than identifying the patient on electronic labels. The fact that Berney does not disclose such means evidences the purpose of Berney's labels: to store analysis data during the time of specimen analysis rather than to record chain of custody data.

[43] *In re Kotzab*, 217 F3d 1365, 55 USPQ2d 1313 (Fed Cir. 2000) ("Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference.

objective evidence.[44] Indeed, a rejection of a claim in a utility application under 35 U.S.C. § 103(a) is a legal conclusion which must be based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of obviousness. The references must provide one of ordinary skill a motivation to combine their respective elements to yield the claimed invention.[45]

In the case of *In re Lee*,[46] the Federal Circuit ruled that findings under 35 U.S.C. 103 must be reasoned ones. The Court further indicated that grounds supporting the findings must be clearly articulated on the record. And the evidence must come from the references, not the examiner's hindsight-based reconstruction of the applicant's claims:

> With respect to Lee's application, neither the examiner nor the Board adequately supported the selection and combination of the Nortrup and Thunderchopper references to render obvious that which Lee described. The examiner's conclusory statements that "the demonstration mode is just a programmable feature which can be used in many different device[s] for providing automatic introduction by adding the proper programming software" and that "another motivation would be that the automatic demonstration mode is user friendly and it functions as a tutorial" do not adequately address the issue of motivation to combine. This factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority. It is improper, in determining whether a person of ordinary skill would have been led to this combination of references, simply to "[use] that which the inventor taught against its teacher." Thus the Board

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See *B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1582, 37 USPQ2d 1314, 1318 (Fed. Cir. 1996).")

[44] MPEP 2143.01 citing *In re Lee*, 277 F3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (discussing the importance of relying on objective evidence and making specific factual findings with respect to the motivation to combine references); See also *In re Dembiczak* 175 F.3d 994, 998, 50 USPQ 1614, 1616 (Fed. Cir. 1999) (disallowing the substitution of broad conclusory statements for evidence).

[45] *In Re Dembiczak*, 50 U.S.P.Q. 2d 1614 (Fed. Cir. 1999).

[46] 61 USPQ2d. 1430, 277 F3d 1338 (2002).

> must not only assure that the requisite findings are made, based on evidence of record, but must also explain the reasoning by which the findings are deemed to support the agency's conclusion.[47]

Contrary to this clear directive, the Examiner's findings are not reasoned ones. To conclude that it would have been obvious to transport Berney's vessels because transporting the vessels allows tracking the vessels, as the Examiner did, does not address the issue whether one of ordinary skill would have modified Berney to produce Appellant's invention. The Examiner has not even attempted to cite objective evidence of obviousness. Her rejection is based in an alleged "conventional practice" combined with the subjective circular assertion that one would transport vessels to track vessels. In fact, Berney does not suggest distributing specimen collection vessels including wireless electronic memory tags to a specimen collection facility. Nor does Berney motivate one to do so. Berney is concerned with tracking information only during the time of specimen analysis. So the Examiner's rejection of Claim 21 as unpatentable over Berney should be reversed.

E. Claims 5, 8, 13 And 18 Are Patentable Over Petrick or Berney in View of Leuenberger.

E.1.Claims 5 and 13 Are Patentable.

The Examiner concludes that it would have been obvious to store data including the identity of a specimen vessel and product information about the vessel on a memory tag. One of ordinary skill would allegedly modify Petrick to include such information 'because vessels (containers) from different suppliers may vary, and therefore such information is important for handling containers properly, and also because information on a supplier and the product is

[47] Id., 61 USPQ2d at 1434 (Internal citations omitted).

always conventionally provided with all manufactured products, especially test tubes (vessels, containers).'[48]

Of course, Petrick is not prior art, but still, the reference fails teach or suggest storing product information on an electronic memory tag attached to a specimen collection vessel. Leuenberger says that paper labels have been used to store product information on blood packs, but that the paper labels exhibit certain disadvantages overcome by the use of microporous plastic film labels.[49] Thus, Leuenberger suggests paper or plastic film labels, but fails to suggest using an electronic memory tag to store product information. Berney discloses storing information on an electronic label in a laboratory during the time of specimen analysis. Neither Petrick, Berney or Leuenberger suggests storing product or manufacturer information on an electronic memory tag at a vessel distribution facility. Even if the Examiner were correct in asserting that product information "is always conventionally provided with all manufactured products,"[50] that fact says nothing about storing that information *on an electronic memory tag*, as Appellant claims. To say that one of ordinary skill would have combined Petrick or Berney with Leuenberger to produce an electronic memory tag having stored thereon manufacturer or product information is merely bridging the gap between the references by using that which Appellant teaches against its teacher. Thus, the Examiner's rejections of Claims 5 and 13 are improper and should be reversed.

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[48] Paragraph 11 of Office Action mailed January 10, 2006.

[49] Col. 1, Lines 18-55 of Leuenberger.

[50] Paragraph 11 of Office Action mailed January 10, 2006.

E.2. Claim 8 Is Patentable.

Claim 8 describes a diagnostic specimen system including a population of collection vessels each having attached thereto both an electronic memory tag and a label having an identifying bar code. Petrick is not prior art to Appellant's application and Berney discloses an electronic label for registering all useful information during the time of analyses of a specimen contained in a test tube. The reference does not teach or suggest a label having an identifying bar code attached to its test tubes. And, although Leuenberger discloses the use of microporous plastic film labels that may include an identifying bar code 16,[51] one of ordinary skill would find no suggestion or motivation to add Leuenberger's bar code to the test tubes disclosed by Berney because Berney's electronic label is provided for registering such information. Therefore, Appellant's claim is patentable in view of the references and the Examiner's rejection of Claim 18 should be reversed.

E.3. Claim 18 Is Patentable.

Petrick is not prior art to Appellant's application and neither Berney nor Leuenberger discloses providing a population of biomedical specimen vessels or storing data on an electronic memory tag at a vessel distribution facility. Neither do the references disclose shipping members of a population of vessels including electronic memory tags from a vessel distribution facility to a specimen collection facility. Thus, the references do not teach or suggest all of Appellant's claim limitations, so the Examiner's rejection of Claim 18 should be reversed.

[51] Col. 2, Lines 5-55 of Leuenberger.

F. Claims 16, 17, 20, 42, and 43 are patentable over Petrick or Berney in View of Hoffman or Fukuzaki.

F.1. Claims 16, 42 and 43 Are Patentable

The Examiner asserted that one of ordinary skill would have combined the electronic signature disclosed in Hoffman or Fukuzaki with Petrick's or Berney's disclosure "specifically for the reasons indicated by Hoffman and Fukuzaki, i.e. for securing electronically transferred data, and because the signature of 'the person under concern' is conventional in all diagnostic procedures."[52] Petrick, however, is not prior art to Appellant's application and Berney does not disclose members of a population of specimen vessels at Appellant's claimed locations. Nor is there any apparent way to store an electronic signature of the donor of a toxicology specimen on Berney's test tubes, since the tags are attached during the time of sample analysis. Also, neither Hoffman nor Fukuzaki suggests including an encoded electronic signature of the donor of a toxicology specimen on an electronic memory tag. Hoffman is concerned with a method of correlative comparison of a biometrics sample for authenticating identification and Fukuzaki discloses an electronic document security system. Neither reference teaches or suggests a specimen vessel having a memory tag containing an encoded electronic signature.

F.2. Claim 17 is Patentable

The Examiner asserts that it would have been obvious to combine Hoffman or Fukuzaki with Petrick or Berney to produce Appellant's Claim 17.[53] Prior art references combined to establish obviousness, however, must teach or suggest all claim limitations.[54] Appellant claims a

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[52] Paragraph 12 of Office Action mailed January 10,2006.

[53] Paragraph 12 of Office Action mailed January 10, 2006.

[54] MPEP 2143.

toxicology specimen system including a population of specimen vessels having wireless electronic memory tags storing data including an identification code for the vessel, the identity of the supplier of the vessel and product information about the vessel. Petrick is not prior art to Appellant's application but, even so, neither Petrick nor Berney teaches or suggests all the elements of Claim 17. Hoffman is concerned with a method of correlative comparison of a biometrics sample for authenticating identification and Fukuzaki discloses an electronic document security system. Neither Hoffman nor Fukuzaki teaches or suggests a toxicology specimen system including a population of specimen vessels having wireless electronic memory tags storing data including an identification code for the vessel, the identity of the supplier of the vessel and product information about the vessel. Therefore, Appellant's claim would not have been obvious to one of ordinary skill and the Examiner's rejection of the claim should be reversed.

F.3. Claim 20 is Patentable

Petrick is not prior art to Appellant's application and Neither Berney, Hoffman, nor Fukuzaki discloses a method that includes providing a population of vessels at a vessel distribution facility, distributing members to a collection facility, or collecting a specimen at the collection facility. Therefore, Appellant's Claim 20 would not have been obvious to one of ordinary skill in the art and the Examiner's rejection of the claim should be reversed.

G. Claims 2 and 10 are Patentable over Berney in view of RD 421048 A.

To establish a *prima facie* case of obviousness, a combination of prior art references must teach or suggest all the limitations of the allegedly obvious claimed invention.[55] Berney does not teach or suggest a specimen system including a population of vessels having members located at a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory. RD 421048 A discloses a method for chemical management for tracking compounds within a chemical synthesis system including identification tags having passive transponders.[56] Modifying Berney to include RD 421048 A's passive transponders does not produce the diagnostic specimen system of Appellant's Claims 2 and 10 because RD421048 A does not disclose applicant's claimed vessel locations. Thus, the claims would not have been obvious and the Examiner's rejections Berney in view of RD 421048A should be reversed.

H. Claims 3-4 and 11-12 are Patentable over Berney in View of Stevens.

The Examiner asserts that it would have been obvious "to improve Berney's container comprising the electronic tag by adding a label with a barcode and providing the same information to the electronic tag in the same way Stevens labeled his container, because this serves the same purpose that Stevens disclosed in his invention, i.e. to 'create a link between the container, the patient and the test request forms', or any other forms associated with using this container."[57]

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[55] Id.

[56] ABSTRACT of RD 421048 A.

[57] Paragraph 14 of Office Action mailed January 10, 2006 quoting Bowman at Column 1, Line 13-18.

Stevens discloses a sample collection tube 20 and a label 40 comprising a permanent portion 50 having a barcode 90 and a peel away portion 70 for affixation to a test request form or to another container or item.[58] Berney discloses an electronic label that provides for registration of *all* useful information required for analysis of a blood sample, however, and thus *eliminates* the need for jotting down and manual transfer of information.[59]

Therefore, Combining Stevens' barcode associated with a manual entry form with Berney's disclosure would destroy Berney's purpose of eliminating manual entry of information, so one of ordinary skill would not modify the references as proposed by the Examiner,[60] and even if one were to make such a modification, the result would still not produce Appellant's claimed vessel locations. Accordingly, the obviousness rejection of each of Claims 3-4 and 11-12 is improper and should be reversed.

I. Claim 38 is Patentable over Berney in View of Bowman.

The Examiner asserted it would have been obvious to modify Berney's specimen collection vessel by adding the tamper-indicating seal disclosed by Bowman "so that any attempted tampering with the specimen will be indicated by at least partial destruction of the seal."[61] Berney discloses electronic memory labels for registering all useful information during blood analyses and Bowman discloses a chain-of-custody bag 10 for the sealing there within during transportation to an analysis site a specimen taken at a remote location.[62] Modifying

[58] Col. 5, Lines 25-27; Col. 6, Lines 19-21; Figure 8 of Stevens.

[59] Col. 1, Lines 30-32 of Berney.

[60] MPEP 2143.01(V.).

[61] Paragraph 15 of Office Action mailed January 10, 2006.

[62] Col. 3, Lines 9-19 of Bowman.

Berney this way, however, is not suggested by the references. Berney is not concerned with transporting vessels from a collection facility to a laboratory, so there is no risk of tampering that needs evidencing. Berney's test tubes are provided with caps 2 that can be removed to permit access to a blood specimen;[63] so adding Bowman's seal to Berney's test tubes would interfere with removal of Berney's cap during specimen analysis. Therefore, the references would not have suggested such a modification,[64] and the Examiner's rejection of Claim 38 should be reversed.

J. Claim 8 is Patentable over Berney in view of RD421048 A, Stevens and Leuenberger.

The Examiner further asserts that it would have been obvious to include product information on a thrice-modified version of Berney "because, first this is a conventional information always provided with the products, and second, because the identity of the supplier may assist in the proper handling the container."[65] Neither of these proffered motives, however, explains why one would be motivated to store supplier information *on an electronic memory tag*, as Appellant claims, rather than marking the product itself, as Leuenberger suggests. Thus, they fail to address the question whether one of ordinary skill would have been motivated to combine the references to produce the *claimed invention*. Arguments made above are also applicable here. Therefore, the Examiner has failed to present a *prima facie* case of obviousness with respect to Claim 8, and the rejection of this claim should be reversed.

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[63] Col. 1, Line 62, Fig. 1 of Berney.

[64] MPEP 2143.01(V.).

[65] Paragraph 16 of Office Action mailed January 10, 2006.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Danny Charles Bowman

Serial No.: 09/737,185 Examiner: Gakh

Filed: December 14, 2000 Art Unit: 1743

For: **PAPERLESS CHAIN OF CUSTODY EVIDENCE FOR LAB SAMPLES**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION UNDER RULE 1.131

JASON BOWMAN does hereby say as follows:

1. I am one of the inventors of the above-identified patent application.

2. I have attached copies of evidence that the above-identified patent application was conceived in the United States or a NAFTA country before November 17, 2000 and applicants were diligent to a constructive redirection to practice from a time prior to November 17, 2000, until December 14, 2000. Dates not specified herein have been redacted but were prior to November 17, 2000:

a. a draft of the application for the PAPERLESS CHAIN OF CUSTODY FOR LAB SAMPLES was developed with the assistance of applicants' lawyers by a date prior to November 17, 2000, and a copy is the attached Exhibit A;

b. a final draft with formal documents for signature was forwarded by counsel on December 5, 2000;

c. The inventors reviewed and approved the application for filing, and the formal documents accompanying the application were signed December 11, 2000, and forwarded to counsel for filing in the PTO on December 14, 2000.

d. from the period beginning at the latest when the "final draft" of the application was developed prior to November 17, 2000 until December 14, 2000, when the application was filed, the inventors of the subject matter of the PAPERLESS CHAIN OF CUSTODY FOR LAB SAMPLES proceeded diligently in all matters regarding the filing of the application.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Jason Bowman

6/2/2004

Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Danny Charles Bowman

Serial No.: 09/737,185 Examiner: Gakh

Filed: December 14, 2000 Art Unit: 1743

For: **PAPERLESS CHAIN OF CUSTODY EVIDENCE FOR LAB SAMPLES**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION UNDER RULE 1.131

DAVID MICHAEL LEWIS does hereby say as follows:

1. I am one of the inventors of the above-identified patent application.

2. I have attached copies of evidence that the above-identified patent application was conceived in the United States or a NAFTA country before November 17, 2000 and applicants were diligent to a constructive redirection to practice from a time prior to November 17, 2000, until December 14, 2000. Dates not specified herein have been redacted but were prior to November 17, 2000:

a. a draft of the application for the PAPERLESS CHAIN OF CUSTODY FOR LAB SAMPLES was developed with the assistance of applicants' lawyers by a date prior to November 17, 2000, and a copy is the attached Exhibit A;

b. a final draft with formal documents for signature was forwarded by counsel on December 5, 2000;

c. The inventors reviewed and approved the application for filing, and the formal documents accompanying the application were signed December 11, 2000, and forwarded to counsel for filing in the PTO on December 14, 2000.

d. from the period beginning at the latest when the "final draft" of the application was developed prior to November 17, 2000 until December 14, 2000, when the application was filed, the inventors of the subject matter of the PAPERLESS CHAIN OF CUSTODY FOR LAB SAMPLES proceeded diligently in all matters regarding the filing of the application.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and such willful false statements may jeopardize the validity of the application or any patent issued thereon.

David Michael Lewis

6/3/04
Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Danny Charles Bowman

Serial No.: 09/737,185 Examiner: Gakh

Filed: December 14, 2000 Art Unit: 1743

For: **PAPERLESS CHAIN OF CUSTODY EVIDENCE FOR LAB SAMPLES**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION UNDER RULE 1.131

DANNY CHARLES BOWMAN does hereby say as follows:

1. Richard Kimberly Paisley is one of the inventors of the above-identified patent application.

2. Richard Kimberly Paisley assigned the above-identified patent application to GBF, Inc.

3. I am an officer of GBF, Inc.

4. Richard Kimberly Paisley in unavailable to GBF, Inc. to provide a Declaration Under Rule 1.131.

5. I am one of the inventors of the above-identified patent application.

6. I have attached copies of evidence that the above-identified patent application was conceived in the United States or a NAFTA country before November 17, 2000 and applicants were diligent to a constructive redirection to practice from a time prior to November 17, 2000, until December 14, 2000. Dates not specified herein have been redacted but were prior to November 17, 2000:

a. a draft of the application for the PAPERLESS CHAIN OF CUSTODY FOR LAB SAMPLES was developed with the assistance of applicants' lawyers by a date prior to November 17, 2000, and a copy is the attached Exhibit A;

b. a final draft with formal documents for signature was forwarded by counsel on December 5, 2000;

c. The inventors reviewed and approved the application for filing, and the formal documents accompanying the application were signed December 11, 2000, and forwarded to counsel for filing in the PTO on December 14, 2000.

d. from the period beginning at the latest when the "final draft" of the application was developed prior to November 17, 2000 until December 14, 2000, when the application was filed, the inventors of the subject matter of the PAPERLESS CHAIN OF CUSTODY FOR LAB SAMPLES proceeded diligently in all matters regarding the filing of the application.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Danny Charles Bowman

6-15-04

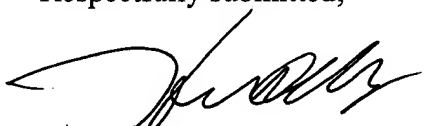
Date

K. Claim 17 is Patentable over Berney in View of RD 421048 A, Stevens, Leuenberger and Hoffman or Fukuzaki.

The Examiner asserts that one of ordinary skill would have combined the encoded electronic signature of Hoffman or Fukuzaki with a thrice-modified version of Berney to produce Appellant's claimed invention.[66] Berney, however, discloses logging information concerning the person under concern in a specimen analysis laboratory, and neither Hoffman nor Fukuzaki suggest storing a signature on an electronic memory tag. Nor is there any apparent way to store an electronic signature of the donor of a toxicology specimen on Berney's labels, since they are attached during the time of sample analyses. Also, Hoffman is concerned with a method of correlative comparison of a biometrics sample for authenticating identification and Fukuzaki discloses an electronic document security system. Neither reference teaches or suggests a specimen vessel having a memory tag containing an encoded electronic signature. Therefore, the Examiner's rejection of Claim 17 should be reversed.

The Examiner's rejection of Claims 1-21, 38, 40-44 should be reversed.

Respectfully submitted,



Howard A. MacCord, Jr.
Registration No. 28,639
MacCord Mason PLLC
P. O. Box 2974
Greensboro, NC 27402
(336) 273-4422

Date: March 27, 2008
File No.: 2552-011

CERTIFICATE OF MAILING

I HEREBY CERTIFY THAT THIS DOCUMENT IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST-CLASS MAIL, IN AN ENVELOPE ADDRESSED TO: **COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450**, ON March 27, 2008
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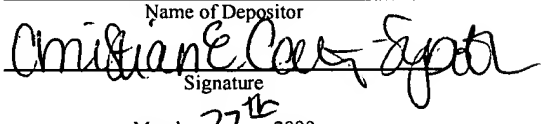
Name of Depositor



Signature

March 27th, 2008
Date of Signature

[66] Paragraph 17 of Office Action mailed January 10, 2006.

8. Claims Appendix

The appealed claims are as follows:

1. A diagnostic specimen system comprising a population of biomedical specimen collection vessels located at and transportable between a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory facility, wherein each of the collection vessels includes a wireless electronic memory tag for non-contact storage and retrieval of information attached thereto such that the tag remains attached to the vessel as the vessel is transported between facilities.

2. A diagnostic specimen system as claimed in claim 1 wherein each electronic memory tag includes a radio frequency transponder.

3. A diagnostic specimen system as claimed in claim 1 wherein each electronic memory tag contains stored data including an identification code for the vessel.

4. A diagnostic specimen system as claimed in claim 3 further including a label imprinted with a bar code attached to each vessel, the bar code identifying the vessel.

5. A diagnostic specimen system as claimed in claim 1 wherein each electronic memory tag contains stored data including the identity of a supplier of the vessel and product information about the vessel.

6. A diagnostic specimen system as claimed in claim 1 wherein an electronic memory tag contains stored data including identifying information about a specimen contained in the vessel and about the specimen donor.

7. A diagnostic specimen system as claimed in claim 6 wherein an electronic memory tag contains stored data further including definition of the analytical tests to be performed on the specimen in the vessel.

8. A diagnostic specimen system comprising:

a population of collection vessels located at and transportable between a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory facility, wherein each of the collection vessels includes a wireless electronic memory tag for non-contact storage and retrieval of information attached thereto such that the tag remains attached to the vessel as the vessel is transported between facilities;

data stored on an electronic memory tag including an identification code for the vessel, the identity of the supplier of the vessel and product information about the vessel, identifying information about a specimen contained in the vessel and about the specimen donor, and definition of the analytical tests to be performed on the specimen in the vessel; and

a label imprinted with an identifying bar code attached to each vessel.

9. A toxicology specimen system comprising a population of collection vessels, each configured to receive and contain a toxicology specimen and having a wireless electronic memory tag attached to the vessel for non-contact storage and retrieval of information, wherein

the population includes members located at and transportable between a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory, wherein each of the collection vessels includes a wireless electronic memory tag for non-contact storage and retrieval of information attached thereto such that the tag remains attached to the vessel as the vessel is transported between facilities.

10. A toxicology specimen system as claimed in claim 9 wherein each electronic memory tag includes a radio frequency transponder.

11. A toxicology specimen system as claimed in claim 9 wherein each electronic memory tag contains stored data including an identification code for the vessel.

12. A toxicology specimen system as claimed in claim 11 further including a label imprinted with an identifying bar code attached to each vessel.

13. A toxicology specimen system as claimed in claim 9 wherein each electronic memory tag contains stored data including the identity of the supplier of the vessel and product information about the vessel.

14. A toxicology specimen system as claimed in claim 9 wherein an electronic memory tag contains stored data including identifying information about a specimen contained in the vessel and about the specimen donor.

15. A toxicology specimen system as claimed in claim 14 wherein an electronic memory tag contains stored data further including definition of the analytical tests to be performed on the specimen in the vessel.

16. A toxicology specimen system as claimed in claim 9 wherein an electronic memory tag contains stored data including an encoded electronic signature of the donor of a toxicology specimen.

17. A toxicology specimen system comprising:

a population of biomedical specimen collection vessels, wherein the population includes members located at and transportable between a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory facility, each vessel having a wireless electronic memory tag attached to the vessel such that the tag remains attached to the vessel as the vessel is transported between facilities, the electronic memory tag including a radio frequency transponder for non-contact storage and retrieval of information; data stored on the electronic memory tags including an identification code for the vessel, the identity of the supplier of the vessel and product information about the vessel, identifying information about a specimen contained in the vessel and about the specimen donor, definition of the analytical tests to be performed on the specimen in the vessel, and an encoded electronic signature of the donor of the toxicology specimen in the vessel; and a label imprinted with an identifying bar code attached to each vessel.

18. A method for electronically storing information on a diagnostic or toxicology specimen vessel and remotely reading information from the vessel comprising:

providing a population of biomedical specimen vessels, each having a wireless electronic memory tag attached thereto, wherein the population includes members located at and transportable between a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory facility;

electronically storing data on one of the electronic memory tags at the vessel distribution facility;

shipping members including the electronic memory tags attached thereto with electronically stored data from the vessel distribution facility to the specimen collection facility; and

reading the stored information from the electronic memory tag with a non-contact electronic reader or scanner at a specimen testing laboratory facility.

19. A method for recording information about a diagnostic or toxicology specimen on a diagnostic or toxicology specimen vessel comprising:

providing a population of biomedical specimen vessels, each having a wireless electronic memory tag attached to the vessel at a vessel distribution facility;

distributing population members including the wireless electronic memory tag attached thereto to a specimen collection facility;

collecting a specimen from a donor in the specimen container at the specimen collection facility; and

electronically storing information about the specimen, donor, and/or tests to be performed on the specimen on the electronic memory tag.

20. A method as claimed in claim 19 further including collecting and storing an electronic signature of the specimen donor on the electronic memory tag at the specimen collection facility.

21. A method as claimed in claim 19 further including transporting the member vessel with collected specimen from the specimen collection facility to a specimen testing laboratory and storing the results of the analytical tests performed on the specimen in the vessel on the electronic memory tag at the specimen testing laboratory.

38. A toxicology specimen system comprising a collection vessel configured to receive and contain a toxicology specimen, a tamper-indicating seal, and wireless electronic memory tag attached to the vessel such that the tag remains attached to the vessel as the vessel is transported, the tag for non-contact storage and retrieval of information and wherein the electronic memory tag contains stored data including an encoded electronic signature of the donor of a toxicology specimen.

40. A diagnostic specimen system as claimed in claim 1 further including an electronic database accessible from the specimen collection facility for storing data entered at the collection facility.

41. A diagnostic specimen system as claimed in claim 40 further including an electronic network connecting the specimen collection facility to the specimen testing laboratory for transmitting data from the collection facility to the testing laboratory.

42. A toxicology specimen system comprising a population of collection vessels, each configured to receive and contain a toxicology specimen and having a wireless electronic memory tag attached to the vessel for non-contact storage and retrieval of information, the memory tag containing stored data including an encoded electronic signature of the donor of a toxicology specimen, wherein the population includes a member at a vessel distribution facility, a member at a specimen collection facility, and a member at a specimen testing laboratory facility and wherein the members are transportable between the facilities and the tag is attached to the vessel such that it remains attached to the vessel as the vessel is transported between facilities.

43. A toxicology specimen system comprising:

a biomedical specimen collection vessel and a tamper-indicating, wireless electronic memory tag attached to the vessel such that the tag remains attached to the vessel as the vessel is shipped to between a between a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory facility, the tag including a radio frequency transponder for non-contact storage and retrieval of information;

data stored on the electronic memory tag including an identification code for the container, the identity of the supplier of the vessel and product information about the vessel, identifying information about a specimen contained in the vessel and about the specimen donor,

definition of the analytical tests to be performed on the specimen in the vessel, and an encoded electronic signature of the donor of the toxicology specimen in the vessel; and

a label imprinted with an identifying bar code.

44. A method for recording information about a diagnostic or toxicology specimen on a diagnostic or toxicology specimen vessel comprising:

providing a population of biomedical specimen vessels, each having a wireless electronic memory tag attached to the vessel, wherein the population includes a member at a vessel distribution facility, a member at a specimen collection facility, and a member at a specimen testing laboratory facility, and wherein each of the vessels includes a wireless electronic memory tag attached thereto such that the tag remains attached to the vessel as the vessel is transported between facilities;

collecting a specimen from a donor in the specimen vessel at the specimen collection facility;

electronically storing information about the specimen, donor, and/or tests to be performed on the specimen on the electronic memory tag; and

collecting and storing the electronic signature of the specimen donor on the electronic memory tag at the specimen collection facility.

9. Evidence Appendix

A. These references were cited by the Examiner in making rejections, and applicant relies on portion of them to show the errors of the rejections. Copies are attached.

Patent Number or Document Number	1st Named Inventor	Examiner Cited in Office Action Dated
6,535,129	Petrick	10 January 2006
5,613,012	Hoffman	10 January 2006
5,777,303	Berney	10 January 2006
5,135,313	Bowman	10 January 2006
EP 1,004,359 A2	Stevens	10 January 2006
5,314,421	Leuenberger	10 January 2006
RD 421048 A		10 January 2006
5,948,103	Fukuzaki	10 January 2006

B. Additional evidence submitted by applicant.

Declarations under Rule 1.131 of Jason Bowman, Danny Charles Bowman and David Michael Lewis, and Exhibits thereto. Copies are attached.

10. Related Proceedings

None.